REMARKS

Claims 4 and 5 are pending in the application. The amendments to the claims have been made to further clarify the presently claimed invention. Support for the amendments to the claims can be found in the claims as originally presented. No new matter has been introduced, and entry of the above revised claims is respectfully requested.

Rejection Under 35 U.S.C. §103(a), Over Sadhu (Chem. Pharm. Bull. 51(5):595-598, 2003) In View of Akamatsu (Dermatology 196:82-85, 1998)

Claim 5 has been rejected under 35 U.S.C. §103(a) as being "obvious" over Sadhu in view of Akamatsu. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Sadhu discloses that prostaglandin inhibitory and radical scavenging (anti-oxidant) activities are assayed to determine the anti-inflammatory and anti-rheumatic properties of various indicated compounds, including macelignan (LA-3) (page 596, left column, second full paragraph). Sadhu further discloses that prostaglandin, reactive oxygen and reactive nitrogen species are closely related to inflammation and rheumatoid arthritis. Sadhu discloses that macelignan (LA-3) possesses antioxidant activity with an IC50 value of 35 uM, but that macelignan (LA-3) is inactive at inhibiting PGE1- and PGE2-induced contractions in guinea pig ilieum in concentrations up to 9×10^{-7} g/ml (270 uM) (paragraph bridging pages 595 and 596). Sadhu further fails to disclose or suggest a method of treating acne by admninistering macelignan.

Akamatsu discloses that an antibiotic metronidazole, which is used to treat acne, inhibits reactive oxygen species (ROS) generated by neutrophils.

Applicants submit that the Examiner has failed to establish *prima facie* obviousness. As discussed above, Sadhu discloses that macelignan fails one of the two tests to demonstrate anti-inflammatory activity. Macelignan fails to inhibit PGE-induced contraction of guinea pig ileum, which is one of the two assays for determining whether a compound has anti-inflammatory properties. Based on Sadhu, the Examiner assumes that macelignan would elicit anti-inflammatory activity because of its antioxidant property. However, the Examiner has failed to consider the Sadhu reference in its entirety, where macelignan fails to inhibit PGE-induced contractions in guinea pig ileum. Therefore, a person of ordinary skill in the art would not conclude that macelignan would be useful as an anti-inflammatory agent.

Moreover, Sadhu fails to disclose or suggest any anti-bacterial properties associated with macelignan. In contrast, the present application at Table 2 demonstrates the anti-bacterial effects

of macelignan. The present application discloses that macelignan treats acne by inhibiting the growth of acne-causing bacteria, not by inhibiting ROS generated by neutrophils. Since Sadhu discloses that the instantly claimed macelignan possesses only anti-oxidant property, and fails to disclose or suggest any anti-bacterial effects of macelignan and further discloses the inadequacies of macelignan as an anti-inflammatory agent because of its failure in the second part of the two part test, the inhibition of PGE-induced contraction of guinea pig ileum, a person of skill in the art would not have had a reasonable expectation of success that macelignan would treat acne nor inhibit the growth of acne-causing bacteria.

Akamatsu fails to resolve or remedy any of the deficiencies in the Sadhu reference because Aakmatsu fails to disclose or suggest macelignan, and therefore, the Akamatsu fails to be combinable with the Sadhu reference to attempt to arrive at the claimed invention. Moreover, Akamatsu fails to relevant to the claimed invention. Therefore, the presently claimed invention is not obvious over the cited references.

Rejection Under 35 U.S.C. §103(a) Over Dorman (Journal of Applied Microbiology 88:308-316, 2000) In View of Woo (Phytochemistry 26(5):1542-1543, 1987 Abstract only)

Claims 4-5 have been rejected under 35 U.S.C. §103(a) as being "obvious" over Dorman in view of Woo. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Dorman discloses assessing volatile oils from a variety of plants for antibacterial activity, including the plant *Myristica fragrans*. Dorman discloses that the volatile oil of nutmeg *M. fragrans* is equally effective against both Gram-positive and Gram-negative microorganisms. However, Dorman fails to disclose or suggest whether macelignan is found in the volatile oil or the non-volatile residue of *M. fragrans.*

Woo discloses isolating macelignan from "the non-volatile residue (20g) after removal of volatile essential oils by steam distillation" (page 1542, left column, first and second paragraphs under 'Experimental'). The full Woo article is attached as Exhibit A.

Applicants submit that the Examiner has failed to establish *prima facie* establishment of obviousness of the presently claimed invention. Dorman fails to be combinable with Woo. Whereas Dorman discloses the volatile oil residue of *M. fragrans* as having anti-bacterial activity, the cited Woo reference discloses that macelignan is found in the non-volatile residue. Therefore, there is a fundamental conflict in the teachings of these references.

The Examiner has simply assumed that the volatile extract of *Myristica fragrans* contains macelignan without any basis in fact. A closer reading of the entire Woo document shows that macelignan is purified from the non-volatile residue of *Myristica fragrans.* Shin et al., Kor. J.

Pharmacogn. 17(3) : 189-199, 1986 (Exhibit B) confirms that macelignan is obtained from the non-volatile ether fraction of *Myristica fragrans* (Abstract). Therefore, in view of the fact the Dorman and Woo references fail to be applicable to the presently clamed invention, and moreover, these references fail to be combinable with each other because of disparate, unrelated and conflicting teachings, the presently claimed invention is not obvious over the cited references.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is hereby authorized to charge JHK Law's Deposit Account No. **502486** for such fees required under 37 CFR §§ 1.16 and 1.17 and to credit any overpayment to said Deposit Account No. **502486**.

Respectfully submitted,

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Dated: February 19, 2010

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